

Applicant : George G. Klee
Serial No. : 09/853,867
Filed : May 11, 2001
Page : 3 of 12

Attorney's Docket No.: 07039-214001 / Diagnostic
Quality Control

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently amended) A method for calibrating a clinical laboratory analytical instrument, comprising:
 - generating control pool data from a commutable control pool, wherein the control ~~peels have pool has~~ target analyte values for an assay;
 - generating patient specimen data from a distribution of test values for the target analyte from patient specimens;
 - determining tolerance limits from the control pool data and the patient specimen data; and
 - adjusting the calibration of the instrument with respect to the tolerance limits.
2. (Original) The method of claim 1, further comprising reducing variation in the patient specimen data prior to determination of the tolerance limits.
3. (Currently amended) The method of claim 1, further comprising tracking the a normalized distribution of the patient specimen data prior to determination of the tolerance limits.
4. (Currently amended) The method of claim 2, further comprising tracking the a normalized distribution the patient specimen data prior to determination of the tolerance limits.

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Applicant : George G. Klee
Serial No. : 09/853,867
Filed : May 11, 2001
Page : 4 of 12

Attorney's Docket No.: 07039-214001 / Diagnostic
Quality Control

5. (Original) The method of claim 1, wherein the tolerance limits comprise at least one of warning limits and action limits.

6. (Original) The method of claim 1, wherein the adjusting step comprises generating a calibration control signal.

7. (Currently amended) A method for calibrating a clinical laboratory instrument, comprising:

- (a) generating a serum control rule by:
 - (i) providing a control pool that is commutable with patient specimen data for a particular target analyte used in an assay, and
 - (ii) determining traceable target analyte values for the control pool;
- (b) generating a patient distribution index by:
 - (i) reducing variation in a patient distribution, and
 - (ii) tracking normalized patient test values for the target analyte;
- (c) determining tolerance limits for the maximum allowable variation of the serum control rule and the patient distribution index;
- (d) comparing the patient distribution index and the serum control rule to detect a bias with respect to the tolerance limits; and
- (e) adjusting the calibration of the analytical instrument to modify the bias.

8. (Currently amended) A computer readable medium encoded with a computer program, the program being arranged such that, when the program is executed, a computer performs ~~the acts of~~ acts comprising:

generating control pool data from a commutable control pool, wherein the control pools have pool has target analyte values for an assay;

generating patient specimen data from a distribution of test values for the target analyte from patient specimens;

Applicant : George G. Klee
Serial No. : 09/853,867
Filed : May 11, 2001
Page : 5 of 12

Attorney's Docket No.: 07039-214001 / Diagnostic
Quality Control

determining tolerance limits from the control pool data and the patient specimen data; and

adjusting the calibration of the an instrument with respect to the tolerance limits.

9. (Currently amended) The ~~program~~ computer readable medium of claim 8, wherein said acts further comprising comprise:
reducing variation in the patient specimen data prior to determination of the tolerance limits.

10. (Currently amended) The ~~program~~ computer readable medium of claim 8, wherein said acts further comprising comprise:
tracking the a normalized distribution of the patient specimen data prior to determination of the tolerance limits.

11. (Currently amended) The ~~program~~ computer readable medium of claim ~~10~~ 9, wherein said acts further comprising comprise:
tracking the a normalized distribution of the patient specimen data prior to determination of the tolerance limits.

12. (Currently amended) The ~~program~~ computer readable medium of claim 8, wherein the tolerance limits comprise at least one of warning limits and action limits.

13. (Currently amended) The ~~program~~ computer readable medium of claim 8, wherein the adjusting step comprises generating of a calibration control signal.

14. (Currently amended) The ~~program~~ computer readable medium of claim 8, wherein said acts further comprising comprise:
generating an advisory with the a calibration control signal.

Applicant : George G. Klee
Serial No. : 09/853,867
Filed : May 11, 2001
Page : 6 of 12

Attorney's Docket No.: 07039-214001 / Diagnostic
Quality Control

15. (Currently amended) The program computer readable medium of claim 8, wherein said acts further ~~comprising~~ comprise:
determining the efficacy of adjusting the calibration ~~adjustment~~ procedure with respect to the tolerance limits.

16. (Currently amended) The program computer readable medium of claim 15, wherein determining the efficacy ~~the determination~~ comprises calculating ~~the a~~ residual RMS error ~~with respect to the tolerance limits~~.

17. (Currently amended) A chemical analyzer comprising a processor responsive to a computer program, the program being arranged such that, when the program is executed, the processor performs ~~the acts of~~ acts comprising:

generating control pool data from a commutable control pool, wherein the control ~~peels have~~ pool has target analyte values for an assay;

generating patient specimen data from a distribution of test values for the target analyte from patient specimens;

determining tolerance limits from the control pool data and the patient specimen data; and

adjusting the calibration of the an instrument with respect to the tolerance limits.

18. (Currently amended) The analyzer of claim 17, said acts further comprising: reducing variation in the patient specimen data prior to determination of the tolerance limits.

19. (Currently amended) The analyzer of claim ~~17~~ 19, said acts further comprising: tracking ~~the a~~ normalized distribution of the patient specimen data prior to determination of the tolerance limits.

Applicant : George G. Klee
Serial No. : 09/853,867
Filed : May 11, 2001
Page : 7 of 12

Attorney's Docket No. 07039-214001 / Diagnostic
Quality Control

20. (Currently amended) The analyzer of claim ~~18~~ 19, ~~said acts~~ further comprising:
tracking ~~the~~ a normalized distribution of the patient specimen data prior to determination
of the tolerance limits.

21. (Original) The analyzer of claim 17, wherein the tolerance limits comprise at
least one of warning limits and action limits.

22. (Currently amended) The analyzer of claim 17, wherein ~~the~~ adjusting the
calibration step comprises generating ~~of~~ a calibration control signal.

23. (Currently amended) The analyzer of claim ~~22~~ 17, further comprising generating
an advisory with the calibration control signal.

24. (Original) The analyzer of claim 17, further comprising determining the
efficacy of the calibration adjustment procedure with respect to the tolerance limits.

25. (Currently amended) The analyzer of claim 24, wherein ~~the determination~~
determining the efficacy comprises calculating ~~the~~ a residual RMS error ~~with respect to the~~
~~tolerance limits~~.

26. (Currently amended) A clinical analytical instrumentation system, comprising a
central computer and a network of chemical analyzers, wherein at least one of the central
computer and the analyzers comprise a processor responsive to a computer program, the program
being arranged such that, when the program is executed, the processor performs ~~the acts of:~~ acts
comprising:

generating control pool data from a commutable control pool, wherein the control
~~pools have~~ pool has target analyte values for an assay;

Applicant : George G. Klee
Serial No. : 09/853,867
Filed : May 11, 2001
Page : 8 of 12

Attorney's Docket No.: 07039-214001 / Diagnostic
Quality Control

generating patient specimen data from a distribution of test values for the target analyte from patient specimens;
determining tolerance limits from the control pool data and the patient specimen data; and
adjusting the calibration of a chemical analyzer ~~the instrument~~ with respect to the tolerance limits.

27. (Currently amended) A method for analyzing data in an analytical laboratory, wherein the laboratory comprises a central computer networked with at least one chemical analyzer, the method comprising:

transferring assay data from the analyzers to the central computer, wherein a processor in the central computer:

generates control pool data from a commutable control pool, wherein the control pools ~~have~~ pool has target analyte values for an assay;

generates patient specimen data from a distribution of test values for the target analyte from patient specimens;

determines tolerance limits from the control pool data and the patient specimen data; and

adjusts the calibration of at least one chemical analyzer with respect to the tolerance limits.

28. (Currently amended) A method for calibrating a clinical laboratory analytical instrument, comprising:

generating a serum control rule from a commutable control pool, wherein the control pools ~~have~~ pool has target analyte values for an assay;

generating a patient distribution index from patient specimens;

determining tolerance limits from the serum control pool and the patient distribution index; and

Applicant : George G. Klee
Serial No. : 09/853,867
Filed : May 11, 2001
Page : 9 of 12

Attorney's Docket No.: 07039-214001 / Diagnostic
Quality Control

adjusting the calibration of the instrument with respect to the tolerance limits.

29. (New) The method of claim 1, wherein said control pool has at least one target analyte with corresponding target analyte values for an assay, and wherein patient specimen data is generated from a distribution of test values for each matching analyte.

30. (New) The method of claim 29, further comprising tracking a normalized distribution of the patient specimen data for each analyte prior to determination of the tolerance limits.